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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,711	04/17/2001	Stephen G. Withers	UBC. P-005 - 2	1131

20350 7590 05/20/2003

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/837,711

Applicant(s)

WITHERS ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this c mmunicati n appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) 51-54 and 56-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-50,55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 4, 2003 has been entered.

The amendment filed March 4, 2003 amending the specification to correct typographical errors has been entered.

Claims 40-70 are pending. Claims 51-54 and 56-70 are withdrawn. Claims 40-50 and 55 are under consideration.

Response to Arguments

Applicants' arguments filed on March 4, 2003, paper No. 19, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-50 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of retaining glycosidases wherein the catalytically active carboxylic acid that is nucleophile is mutated to form an oligosaccharide using a specific glycosyl fluoride as a donor and a specific acceptor, does not reasonably provide enablement for a method for synthesizing any oligosaccharide using any glycosidase and any donor and acceptor molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are

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summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

Claims 40-50 and 55 are so broad as to encompass method of use of any glycosidase both retaining and inverting, in which any one of the two catalytic carboxylic amino acids is mutated, in a stereospecific reaction using any donor and acceptor. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of glycosidases having different structures, functions and substrate specificities, and donors and acceptors broadly encompassed by the claims. The disclosure teaches the method of use of a retaining glucosidase mutant, AbgE358A, with α -glucosyl fluoride or α -galactosyl fluoride as a donor and arylglycosides as acceptors to form oligosaccharides (Tables 1-3). The Declaration under 37 CFR 1.132 by Dr. Withers filed June 3, 2002 teaches the use of a nucleophile mutant of another retaining glycosidase, LacZ β -galactosidase, with α -galactosyl fluoride as a donor and two acceptors to form oligosaccharides. Therefore, only α -glucosyl fluoride and α -galactosyl fluoride are used as a donor. The art published after the filing date of the instant application teaches a few examples of other retaining glycosidases mutated at a catalytically active carboxylic acid

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nucleophile with a respective glycosyl fluoride as a donor. Thus, no donors other than a respective glycosyl fluoride and a limited number of acceptors are known to be used up to date. However, the claims encompass any donor-acceptor pair irrespectively of the original substrate specificity of a glycosidase. Therefore, based on the instant disclosure and the state of the art, it is unpredictable whether any glycosidase when mutated at any one of the two catalytically active carboxylic amino acids will catalyze coupling of any glycosyl donor and any glycoside acceptor having opposite stereochemical configurations by either inverting or retaining mechanism.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use any mutant glycosidase with any donor and any acceptor other than a retaining glycosidase mutated at a nucleophile catalytically active carboxylic acid with a respective glycosyl fluoride and acceptor to form an oligosaccharide in a manner reasonably correlated with the scope of the claims. Without sufficient guidance, using any mutant glycosidase with any donor other than glycosyl fluoride and any acceptor is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-50 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,716,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a method of coupling a glycosyl donor and a glycoside acceptor having opposite stereochemical configurations using a mutant glycosidase.

Claims 40-50 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,284,494. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a method of coupling a glycosyl donor and a glycoside acceptor having

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opposite stereochemical configurations using the *Agrobacterium* β -glucosidase E358A mutant as defined in claims 1 and 2 of U.S. Patent No. 6,284,494.

Applicants consideration for filing a TD stated in Response filed June 3, 2002 and the current Remarks (page 19) is noted. The rejections are maintained until TD is filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner

May 16, 2003